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14. ABSTRACT
There exists an insufficient amount of research about the symptoms, symptom distress and the trajectory oncadjuvant treatment for breast cancer is complete. Though women get on with living after therapy, some still experience physical symptoms and emotional concerns. The life long consequences of breast cancer treatment musrecognized, addressed and managed if survivors are to enjoy the lives they will go on to live. Research during critical time is essential. Young women, who suddenly feel older because of menopausal symptoms sustained as a result of life-saving therapies, have the potential to develop serious problems. The specific aims of the proposed study were to: (1) Identify the full scope of symptoms and symptom distin women with breast cancer post adjuvant treatment; (2) Develop a comprehensive instrument to measure symptoms symptom distress in women with breast cancer post adjuvant treatment; (3) Develop a grant proposal to support thometric testing of the new instrument. This cross-sectional, correlational study was guided by the UCSF Symptom Management Conceptual Model. After approval from the Health and Behavioral Science Review Board and informed consent from the participants, the tr obtained data from 100 women (50 one to six months after therapy; 50 six to twelve months after therapy) using battery of instruments measuring uncertainty (Mishel Uncertainty in Illness Scale), menopausal symptoms (Breast Cancer Prevention Trial Checklist), and symptom distress (McCorkle Symptom Distress Scale, Symptom Checklist-9Revised, Functional Assessment of Cancer Therapy-Breast). Descriptive statistics provided information on demographic and medical information. Rank/ordering identified the most prominent/persistent symptoms causing distress. The symptoms are in the process of being incorporated into a new and comprehensive instrument to measymptom distress. The psychometrics of the new instrument will be tested in future studies.

15. SUBJECT TERMS
Breast Cancer, Symptoms/Symptom Distress, Instrument development

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Dr. Marcia. M Boehmke's Final Report

The Development of a Comprehensive Instrument to Measure Symptom Distress in Women with Breast Cancer After Treatment Completion

Introduction

As women attempt to integrate the diagnosis of breast cancer into their lives, functioning and quality of life issues arise. It has been postulated that weight gain, menopausal symptoms, and sexuality become prominent sources of symptom distress in the months and years after adjuvant therapy (Knobf, 2000), but little is known about the actual symptom experience, symptom distress and symptom trajectory after adjuvant treatment is complete. Furthermore, there are no comprehensive instruments to measure symptom distress in women with breast cancer during this time period.

The specific aims of this study are to: identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment, develop a comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after adjuvant treatment, and eventually test this new instrument. The study is guided by the UCSF Symptom Management Conceptual Model. Data from 100 women (50 one to six months after therapy; 50 six to twelve months after therapy) will be obtained using a battery of instruments measuring uncertainty (Mishel Uncertainty in Illness Scale), menopausal symptoms (Breast Cancer Prevention Trial Checklist), symptom distress (McCorkle Symptom Distress Scale, Symptom Checklist-90-Revised), and functioning (Functional Assessment of Cancer Therapy-Breast). Descriptive statistics will analyze demographic and medical information. Rank/ordering will identify the most prominent and persistent symptoms causing women distress. These symptoms will then be incorporated in a new and comprehensive tool to measure symptom distress.

Body

The first aim of this study was to identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment.

<u>Spring 2004</u>:

- Course: Oncology for Scientists I taken at Roswell Park Cancer Institute: Gain an understanding of cancer pathology and symptomatology. The course consisted of information on malignant transformation, growth and spread of cancer, genetic mutation, and epidemiology. This knowledge provided an in depth understanding of the cancer process and the resultant cancer treatments and symptoms encountered. Information from this course also provided insight into individual susceptibility to develop cancer both from a compromised immune system, epidemiology, or genetic predisposition.

- I worked closely with Dr. Joyce Yasko, the Director of Research Protocols at Roswell Park. Here I became acquainted with the practical application of three types of studies: pharmacologic, investigative, and cooperative. The role of the research nurses, their training, as well as monitoring studies for adherence to protocols was a great part of this experience. I attended the Scientific Review Committee where I learned how research protocols are reviewed for patient risk as well as plans to deal with adverse outcomes. This insight will be helpful as I prepare future research studies. Meeting with the budget chair at Roswell provided insight on how to prepare a research proposal and budget in concert. As a new researcher, I give great attention to the development of research protocols while giving budgetary requirements less attention. Working with Dr. Yasko I learned that research protocols and the budget should be done in concert. Observing budgetary meetings provided additional information on the feasibility of performing studies and staying on target as to costs.
- Course: Psycho-Social Measurement and Questionnaire Construction taken in the School of Nursing at the University at Buffalo. This course focused on psychometric theory and its application in health and behavioral sciences. Content included scaling methods, in depth evaluation of the reliability and validity of an instrument, factor analysis, and construction of survey questionnaires and attitudinal rating scales. This information will be invaluable as I develop my new comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after treatment completion.
- Worked on the required Department of Defense written protocol. Permission was sought and received from the University at Buffalo Health Sciences Internal Review Board to proceed with the study. Permission was sought and received to use the battery of instruments in this study.

<u>Fall 2005:</u>

- Course: Oncology for Scientists II at Roswell Park Cancer Institute. This course was a sequel to the course in the Spring of 2004 and focused on biostatistics and organ-specific cancers. It provided information about specific cancers, their diagnosis, treatment and prognosis.
- Subject recruitment was delayed until late Fall 2004 because the written protocol was not approved by the Department of Defense until late August with actual letter approving the protocol not received until late October. Subject recruitment was started November 1st 2004. To date 57 women (27 in group one and 30 in group two) have been recruited and have completed the questionnaires. Preliminary data analysis using descriptive statistics shows the following findings:
  - McCorkle Symptom Distress Scale-> the most distressing symptoms are insomnia, fatigue, diminished concentration, and diminished outlook.
  - Mishel Uncertainty in Illness Scale-> most frequent concern centers on future change in health status. Women felt well informed by

their physicians, they could depend on them, and they were given information in clear, understandable terms.

- Breast Cancer Prevention Trial Checklist-> most frequent and distressing symptoms were joint pain, muscle stiffness, weight gain, forgetfulness, problems with appearance, numbness and tingling, night sweats, and early awakenings. It should be mentioned that most of the women preferred this questionnaire and felt that it was the one that captured their symptoms and distress the most accurately.
- Functional Assessment of Cancer Therapy – Breast-> two concerns were clear: they experienced a lack of energy and were worried about family members getting the disease. Most women reported support from family and friends and that they were able to carry on with their lives.
- Symptom Checklist-90-Revised-> sore muscles, trouble sleeping, low energy, and problems remembering were the chief symptoms identified as distressful. Most women did not like this questionnaire as there are many psychological/psychiatric questions and the majority of women felt strongly that they were not applicable.

The CARES tools was eliminated from this study after consultation with Drs. Brown, McCorkle, and Knobf, as it was long and included all the same constructs in the other five questionnaires.

<u>Spring 2005:</u>

- Continue subject recruitment, data entry, and data analysis.
- Work with a gynecologist/endocrinologist to learn more about menopausal pathology and symptomatology.

Aim two was to develop a comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after treatment completion.

- The new instrument will use the BCPT questionnaire as a baseline tool and eliminate the symptoms women generally scored as zero while incorporating the above stated symptoms and concerns. Of particular interest is the fact that, while some symptoms abate slightly in the second group (7 to 12 months after treatment), menopausal symptoms and neuropathies persist and truly affect functioning and quality of life.
- Data entry and preliminary analyses (descriptive statistics) are complete. Based on these findings the new instrument will be comprised five constructs (physical symptoms, menopausal symptoms, cognitive impairment, body image changes, and uncertainty) with approximately five items under each construct. Of interest is that when some questions are read and answered by the women, they voice a sense of relief that these symptoms occur, almost validating how they feel.

<u>Fall 2005</u>

- Recruitment continued most of the Fall until 100 subjects (50 from 0-6 months after treatment and 50 from 7-12 months) after treatment was achieved. Recruitment was completed in December of 2005. Interestingly data collection (completing the 5 questionnaires) should have taken 45 minutes. However, because I was visiting the women at home and because they had not seen a healthcare provider in upwards of 3 months visits often took up to 2 hours. Women and their families had many concerns and questions. Field notes were kept and the anecdotal comments will lead to future research.

Spring 2006

- Data entry was completed by late January 2006.
- Preliminary data analysis (descriptive statistics) was completed by late February 2006.
- Findings:

  The following constructs emerged:

  1. Physical symptoms-> chief among these symptoms were fatigue, muscle pain, and peripheral neuropathy.
  2. Menopausal symptoms-> chief among these were hot flashes, night sweats, early awakening, and impaired sexual functioning.
  3. Cognitive impairment-> women voiced concern over memory loss, distraction, and not being able to think of anything beyond their cancer diagnosis. Interestingly this was also expressed by women close to one year after their treatment had been completed. This appeared to be an ongoing problem.
  4. Body image changes-> even though most women in the study had undergone lumpectomies or lumpectomies and sentinel node biopsy, all women reported some sense of feeling “scarred”. Many reported feeling lopsided and uncomfortable with their image. Interestingly hair loss was NOT reported as an issue but as a “badge of courage”. Many women refused to wear anything on their heads, and did so only if it upset others. Seeking some control over their lives, many elected to shave their heads. Family members and/or friends often assisted with this as a sign of support.
  5. Uncertainty-> most women voiced some level of concern about the future. As noted above, data collection was originally forecasted to take about 45 minutes (and that in reality was the amount of time the questionnaire required for completion). However, after they completed the questionnaires they and often their significant other wanted to “talk with a nurse”. They had many questions and/or concerns. Many felt that while undergoing treatment they

were “fighting their cancer”. After treatment completion they lived in the infamous “black hole” waiting for the other shoe to drop.

The third aim was to develop a grant proposal to support the psychometric testing of the new instrument.

Summer 2005

- To that end, instead of taking a grantsmanship course at the University at Buffalo, Dr. Jean Brown thought it would be more beneficial if I went to UNC-Chapel Hill School of Nursing and took part in the Grant Writing Institute. The institute consists of five days of education and writing guided by Dr. Sandra Funk, a nationally known and funded nurse researcher. This week-long institute was designed so that participants will author a successful research grant for federal funding.

Future Funding

Fall 2006

- Federal funding (NCI or NIH) will be sought to test the new instrument. The grant writing proposal is projected for Fall 2006 or Spring 2007. I will test the instrument in Buffalo, New York and Dr. M. Tish Knobf (consultant) has agreed to test the instrument at Yale, New Haven Medical Center. The new instrument has potential to identify symptom distress not only in women after treatment, but during treatment as well. No one instrument currently available incorporates the five constructs identified in this study. Once symptom distress can be accurately measured, appropriate interventions can be designed to reduce symptom distress.
- National funding (Oncology Nursing Society) will be sought to further investigate concerns/questions women shared in the course of completing the questionnaires. A record has been kept of their anecdotal comments, comment on the questionnaires, and field notes. This uncertainty needs further investigation. An intervention to support these women long after treatment completion is desperately needed. To date, little exists in Western New York to support these women.

Key Research Accomplishments

- The most prominent and distressing symptoms were: fatigue, muscle & joint pain, peripheral neuropathy, and menopausal symptoms (hot flashes, night sweats, early awakening, and sexual dysfunction)
- Identification of body image concerns specifically scarring and lopsidedness.

- Uncertainty: women voiced concerns over "being alone after treatment" and frightened about the even the smallest changes in their health.
- Development of a new instrument based on the five constructs identified by women in this study. Four to five items/questions comprise each of the five constructs.

Reportable Outcomes

- Abstract of preliminary findings were presented at the Era of Hope meeting in June 2005 in Philadelphia.
- A podium presentation of results of this study will be presented at the 17th International Nursing Research Congress in Montreal, Canada (July 2006)
- A poster presentation of the results of this study will take place at the 14th International Conference on Cancer Nursing in Toronto, Canada (October 2006)
- A manuscript concerning the development of the new instrument is projected for Fall 2006 (Cancer Nursing)
- A manuscript describing the concerns of women post-treatment based on anecdotal comments and field notes is projected for Fall 2006
- (Oncology Nursing Forum)

Conclusion

Women continue to experience side effects of treatment and symptoms well after the completion of adjuvant therapy. Muscle and joint pains, neuropathies, and menopausal symptoms persist in the year after treatment and truly affect their functioning and quality of life. Women also expressed feelings of aloneness and worry about their future. As health care providers we must be cognizant of these persistent symptoms and women's feelings and concerns once treatment is over. Understanding their symptoms and resulting distress as well as keeping women connected with their health care provider could enhance their quality of life.

References

Knobf, M. Tish. (2000). Symptom distress before, during and after adjuvant breast cancer therapy. *Developments in Supportive Cancer Care, 4*(1), 13-17.

Appendices

The Following are Abstracts to be Presented in the Summer & Fall:

"A New Comprehensive Instrument to Measure Symptom Distress in Women with Breast Cancer". 17th International Nursing Research Congress, Sigma Theta Tau, Montreal, Canada. July 2006; Podium Presentation.

"A New Comprehensive Instrument to Measure Symptom Distress in Women with Breast Cancer". 14th International Conference on Cancer Nursing. Toronto, Canada. October, 2006 Poster.

Abstract to be Presented in Montreal for the 17th International Nursing Research Congress

A New Comprehensive Instrument to Measure Symptom Distress in Women with Breast Cancer

Background: There exists an insufficient amount of research about the symptoms, symptom distress and the trajectory once adjuvant treatment for breast cancer is complete. Though women get on with living after therapy, some still experience physical symptoms and emotional concerns. The life long consequences of breast cancer treatment must be recognized, addressed and managed if survivors are to enjoy the lives they will go on to live.
Specific Aims: (1) Identify the full scope of symptoms and symptom distress in women with breast cancer post adjuvant treatment; (2) Develop a comprehensive instrument to measure symptoms and symptom distress in these women.
Design: This cross-sectional, correlational study was guided by the UCSF Symptom Management Conceptual Model.
Sample: 50 women (25 one to six months after therapy; 25 seven to twelve months after therapy) were recruited for this study and given a battery of instruments including: Mishel Uncertainty in Illness Scale, Breast Cancer Prevention Trial Checklist, the McCorkle Symptom Distress Scale, Symptom Checklist-90-Revised, and the Functional Assessment of Cancer Therapy-Breast.
Analysis: Descriptive statistics analyzed demographic and clinical information. Rank/ordering identified the most prominent/persistent symptoms causing women distress.
Findings: Five constructs were identified: physical symptoms, menopausal symptoms, cognitive impairment, body image changes, and uncertainty about the future. Approximately four questions will comprise each construct for a total of 20 scored items.
Conclusions: No current instrument incorporates all the symptomatology and/or concerns expressed by women in this study as causing distress. The new instrument will provide healthcare works with a more accurate assessment of symptom distress experienced by women after diagnosis and treatment completion.
Implications: The new instrument will allow for a more precise assessment of the distress experienced by women diagnosed and treated for breast cancer. Earlier and a more accurate identification of symptoms will lead to appropriate interventions.

Abstract to be presented in Toronto for the 14th International Conference on Cancer Nursing

A New Comprehensive Instrument to Measure Symptom Distress in Women with Breast Cancer

Treatment for breast cancer is constantly evolving with subsequent alteration in symptoms, symptom distress and symptom trajectory. Current instruments used to measure symptom distress developed in the 1970's do not reflect the symptoms and symptom distress experienced. Women continue to encounter physical symptoms and emotional concerns long after treatment completion. The life long consequences of breast cancer treatment must be recognized and managed if survivors are to enjoy the lives they will go on to live.

The aims of this study were to: (1) Identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment; (2) develop a comprehensive instrument to measure these symptoms and symptom distress.

A cross-sectional, correlational study guided by the UCSF Symptom Management Conceptual Model guided this study. One hundred women were recruited and given a battery of instruments: Mishel Uncertainty in Illness Scale, Breast Cancer Prevention Trial Checklist, the McCorkle Symptom Distress Scale, Symptom Checklist-90-Revised, and the Functional Assessment of Cancer Therapy-Breast.

Descriptive statistics analyzed demographic and clinical information. Rank/ordering identified the most prominent/persistent symptoms causing distress. Five constructs were identified: physical symptoms, menopausal symptoms, cognitive impairment, body image changes, and uncertainty. Consequently, a new instrument incorporating these constructs will be developed and tested.

The new instrument will allow healthcare providers to more accurately assess symptom distress experienced by women undergoing current therapies as well as after treatment completion. Identifying symptoms and symptom distress earlier and more accurately can lead to the initiation of more appropriate interventions strategies.